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09/599,890 06/21/00 RAJOPADHYE

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EXAMINER

HM12/0404

DUPONT PHARMACEUTICALS COMPANY
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LEGAL PATENTS
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WILMINGTON DE 19898

BALASUBRAMANIAN, V

ART UNIT

PAPER NUMBER

1624

DATE MAILED:

04/04/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/599,890

Applicant(s)
Rajophadye et al.

Examiner
Venkataraman Balasubramanian

Group Art Unit
1624



☐ Responsive to communication(s) filed on _____

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-75 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-75 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 1-75 are pending.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6 and 42-46, drawn to compound bearing indazole nonpeptide Ia or Ib as targeting moiety not bound to surfactant or bound to a surfactant wherein X^{1d} , X^{2d} , X^{3d} , X^{4d} , are all carbon and a chelator, classified in class 548, subclass 361.1 and various other classes and subclasses depending upon the preferred embodiments of chelating group and other hetero ring substituents.
- II. Claims 1-6 and 42-46, drawn to compound bearing indazole nonpeptide Ia or Ib as targeting moiety not bound to surfactant or bound to a surfactant wherein X^{1d} , X^{2d} , X^{3d} , X^{4d} , are nitrogens and carbons and a chelator not provided for in invention I, classified in class 546, subclass 119, class 544, subclass 238, class 544, subclass 262, class 544, subclass 405, class 544, subclasses 180, 182, and various other classes and subclasses depending upon the preferred embodiments of chelating group and other hetero ring substituents.
- III. Claims 1-6 and 42-46, drawn to compound bearing indazole nonpeptide Q is any one of the two peptide recited in claim 2 as targeting moiety not bound to surfactant or bound to a surfactant and a chelator, classified in classes various subclasses various

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depending upon the preferred embodiments of chelating group and other hetero ring substituents.

- IV. Claims 7-10 and 58-64, drawn to a kit comprising compound bearing indazole nonpeptide Q, with or without chemotherapeutic agents, and radiosensitizer, classified in class 206, subclass 569 and others upon the preferred embodiments of Q, other hetero rings, chelating group and structural make-up of chemotherapeutic agents and radiosensitizer.
- V. Claims 11-30, 47-49, 56-57 and 65-67, drawn to multiple compositions, classified in class 514, subclass 221, class 514 subclasses various depending upon the preferred embodiment of chelator group, diagnostic or therapeutic or radiopharmaceutical or X-ray contrast agent (eg. class 424, subclass 9.4, 9.5, 9.51 etc).
- VI. Claims 31-42, 50-55 and 68-74 drawn to multiple method of use of compound bearing indazole nonpeptide Q, with or without chemotherapeutic agents, and radiosensitizer classified in class 514, subclass 221, class 514 subclasses various depending upon the preferred embodiment of chelator group, other variables hetero rings, structural make-up of chemotherapeutic agent and radiosensitizer.
- VII. Claim 75 drawn to a process for preparation of diagnostic or therapeutic metallopharmaceutical classified in class 514, and others subclasses various depending upon the preferred embodiment of targeting moiety and chelator which are not structurally defined in the claim.

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If any one of the invention I-III is elected, applicants should elect a suitable chelating group and working example for examination of elected invention . In addition, applicant may elect a specific composition and a specific method of use for a specific disease form inventions V and VI respectively.

If invention IV (ie. kit) is elected applicant should elect any one of the targeting moiety as in invention I-III and chelating group, an appropriate chemotherapeutic agent/ radiosensitizer if applicable and working example for examination of elected invention .

If invention V is elected, applicants should elect any one of the targeting moiety as in groups I-III and chelating group, a specific intended use as recited in invention and working example for examination of elected invention.

If invention VI is elected , applicants should elect i) a specific metal,
ii) a specific chelator group and iii) a specific target moiety, namely, indazole nonpeptide, with working example and iv) a specific disease for examination of the elected invention .

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are independent and distinct from each other because they are directed to structurally dissimilar compounds that lack common core namely indazole vs isomeric pyridinopyrazoles vs isomeric pyridazinopyrazoles vs isomeric pyrimidinopyrazoles versus pyrazinopyrazole vs isomeric triazinylpyrazoles vs tetrazinylpyrazole. Consequently, the inventions have different classifications and require separate prior art searches. They can be made and used independently. Art which may render obvious or anticipate one of the groups would not necessarily

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do the same for the other group. Each can support a patent as the compounds of each group are capable of being utilized alone not in combination with other members listed in the Markush group.

Search of these class of compounds with variants permitted would pose a serious burden.

Inventions I-III and IV are related as product and process of use of the product as kit.

They are distinct from each other as there is no required combination. The kit can be used independently. Prior art which anticipates or renders inventions I-III obvious may not be applicable to the kit. The issues of patentability of kit such as 112 issues and enablement may not be applicable to compounds of Inventions I-III.

Inventions I-III and V are related as product and multiple composition for different intended use of the composition. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the composition for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different composition of using that product (MPEP § 806.05(h)). In the instant case, the compound of claim 1 can be used as therapeutic radiopharmaceutical for cancer, arthritis etc as well as SPECT or PET diagnostic agents or ultra sound contrast agents as evidenced by applicants claims. Similarly, it is clear from the claims that the process of using can be practiced with materially different products containing a non radioactive material as well as radioactive metals.

Similarly the ultrasound contrast agents, invention XIII is independent and distinct

Inventions I-III and VI are related as product and multiple method of use The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using

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variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Due to the distinct nature of the inventions a restriction is set forth in writing.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on weekdays from 8.30 AM to 5.00 PM.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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VB

V. Balasubramanian (Bala)

3/26/2001

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